![DeVilbiss Healthcare logo]

CLINICAL OVERVIEW:
DeVilbiss IntelliPAP® AutoAdjust®

Autotitrating positive airway pressure (PAP) devices have been on the market for 15 years. DeVilbiss Healthcare, in an effort to illuminate and clarify primary clinical concepts surrounding Autotitrating PAP devices and the unique operation of the DeVilbiss IntelliPAP AutoAdjust, offers this document covering information on a variety of pertinent topics:

- Brief history of Autotitrating devices
- Overview of the purposes and functions of Autotitrating devices
- Description of operational elements common to Autotitrating devices
- Detailed examination of the DeVilbiss AutoAdjust device history, including:
  > the algorithm, with the Precision Laminar Pneumotach™ and the Event Set Measurement™
  > how to customize settings to provide optimal therapy for individual patients
  > an overview of the patient therapy data available through new DeVilbiss reporting tools
- Discussion of independent performance testing/comparisons
- Overview of independent studies on the clinical value of Autotitrating devices
- References

HISTORY

When Autotitrating PAP devices appeared commercially in United States in the mid-1990s, there were a variety of operational theories and technologies offered. Some early devices had major limitations which perpetuated an overall negative impression of how *all* Autotitrating units functioned.

The first Autotitrating unit, cleared for marketing by the Food and Drug Administration (FDA), responded very aggressively to obstructive apneas which caused arousals and consistently woke patients. The second and third Autotitrating units cleared for market, the DeVilbiss AutoAdjust and a French device respectively, were viable and efficacious devices with carefully crafted algorithms. The fourth device used snoring as the only responding event, missing some, if not all apneas and hypopneas; it also woke patients. The advantages and accolades that should have surrounded the DeVilbiss and French Autotitrating units were overshadowed by the negative publicity surrounding the other two devices. The DeVilbiss AutoAdjust in particular was well received by physicians and clinicians as having definitions and responses comparable to those used in sleep labs.

In 2002, the American Academy of Sleep Medicine (AASM) accepted the use of Autotitrating PAP devices for patients with obstructive sleep apnea (OSA) with their publication, *Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: an update for 2007*.[1] This landmark paper confirmed the medically therapeutic value of Autotitrating devices in the treatment of OSA in adult patients.

PURPOSE AND FUNCTION

Currently there are three primary functions of Autotitrating PAP devices:

- **Treatment of chronic Obstructive Sleep Apnea**
  Autotitrating devices effectively treat OSA while taking into account REM-related apneas, positional apneas and night-to-night variability, none of which are accounted for by fixed continuous positive airway pressure (CPAP) devices. Autotitrating PAP devices identify and respond to obstructive apneas and other defined abnormal breathing events by automatically increasing or decreasing pressures as determined by a complex algorithm unique to each Autotitrating device.[3]

- **Collection of detailed patient therapy data**
  Patient therapy data provides information to monitor and/or troubleshoot therapy issues that might require clinical intervention post titration. The data also provides the information necessary to evaluate a patient's progress and to diagnose therapy concerns such as bad mask fit, mouth-breathing and/or low usage. Early response to these issues is crucial to increasing the likelihood of long-term patient adherence.[19] Patient therapy data may also be required to determine insurance reimbursement approval.

- **Attended or unattended PAP titration studies**[3]
  Autotitration devices provide medically accepted OSA therapy for patients who, for liability purposes, require therapy prior to lab titration. Within limitations, Autotitrating devices can be used in attended or unattended sleep studies to determine fixed CPAP for patients.

OPERATIONAL COMMONALITIES

Some elements are common to all manufacturers' Autotitrating devices:

- Internal components
  - > Hardware
  - > Algorithms
- Responding Events – Respiratory events that trigger a therapy response
- Non-Responding Events – Respiratory events that do NOT trigger a therapy response
- Therapy Data-Collecting and Reporting

Internal Components

Hardware

In order for an Autotitrating PAP to measure breathing patterns properly and detect abnormal events, flow and pressure must be communicated to the algorithm as a high-quality signal. Signals that contain random noise do not reliably indicate abnormal events in breathing patterns.

Always used in the DeVilbiss AutoAdjust devices, although absent from some other early Autotitrating units, pneumotachometers are now recognized as the optimal solution for measuring air flow volume over time. Most devices use flow sensors to translate their pneumotach's measurements into signals that can be used to detect flow patterns. The principle behind the use of pneumotachometers and flow sensors is that *flow* patterns indicate corresponding *breathing* patterns.

Autotitrating PAPs also use a pressure transducer to deliver precise pressure levels. The type and quality of these devices can vary depending on sensitivity levels and tolerance specifications.

Algorithms

An algorithm is defined as a set of rules for solving a problem within a finite number of steps. Essentially, algorithms are calculations, embedded in the PAP's firmware, that use flow and pressure signals to solve several Autotitrating 'problems':

- Scoring (calculating) breathing events
- Identifying abnormal events based on a defined set of criteria
- Determining if and how quickly to adjust the delivered pressure in response to an event

Algorithms vary from manufacturer to manufacturer with regard to scored events, the response to the scored event, and the speed with which the response is delivered.

A small number of Autotitrating devices provide the ability to adjust event definitions. These adjustable devices, with response triggers customized to the patient's needs, provide an advantage in properly managing OSA patients.

Responding Events

Responding events are breathing events that, when present, trigger a response to increase pressure and, when absent, trigger a response to decrease pressure. All Autotitrating device manufacturers use a unique formula of responding events, but two events are common to all current Autotitrating PAPs:

- Obstructive apneas – occur when patient airways close and breathing cannot occur
- Hypopneas – occur when patient airways are partially closed and breathing is limited

Obstructive Apneas

All manufacturers' Autotitrating devices respond to obstructive apneas by increasing pressure; however every manufacturer has a unique definition of an obstructive apnea which is dependent on their algorithm's detection and response capabilities. A few manufacturers allow professionals to adjust obstructive apnea definition and create customized patient therapy.

Hypopneas

All Autotitrating device manufacturers increase pressure in response to their unique definition of a hypopnea event. A few manufacturers allow adjustments to hypopnea definition for therapy customization.

Snoring versus Flow Limitation

Snoring and flow limitation are similar in that both may occur prior to obstructive apneas and/or hypopneas. All Autotitrating PAPs are proactively programmed to increase pressure in response to snores or flow limitations to prevent the occurrence of obstructive apneas and hypopneas. There is conflicting evidence as to which parameter allows the earliest response.

Non-Responding Events

Non-responding events are breathing events that are identified and logged without triggering a pressure response. If *non-responding* events are present in conjunction with *responding events*, some Autotitrating units prohibit pressure increases because additional pressure could cause additional non-responding events. Most Autotitrating devices have two non-responding events in common:

- Leaks – usually caused by mouth breathing or mask fit/seal leaks
- Non-obstructive apneas – caused by a PAP-induced reduction in CO_2

Although not common to most Autotitrating units, some include expiratory puffs as non-responding events.

Leaks
Autotitrating units do not increase pressure in response to leaks because higher pressures could cause higher leak rates. (Example: mouth breathers or excessive mask leak) Reporting leaks is valuable to therapy analysis however, because leaks may distort some algorithmic functions.

Non-Obstructive Apneas (NOA)
Non-obstructive apneas, including complex sleep disordered breathing (CSDB), *may* occur during OSA therapy. These non-obstructive apnea events occur if the PAP's pressure reduces carbon dioxide levels in the patient's system. Without the proper CO_2 stimulus, the brain will fail to trigger breathing and a non-obstructive apnea will occur. Most Autotitrating manufacturers do not increase pressure in response to non-obstructive apneas because higher pressures will reduce CO_2 levels further; however, it is important to report non-obstructive apneas for two reasons: *clinically*, if the NOA incidence is high, clinicians may want to investigate central apneas in a lab setting; and *mechanically*, if pressures are not rising as expected, checking the non-responding event index (NRI) may eliminate returning the unit for repair when it is operating normally.

Non-obstructive apneas mimic central apneas. Central apneas occur when the autonomic nervous system fails to trigger breathing as a response to the CO_2 stimulus. Sleep labs are able to properly identify central apneas using muscular effort, EEG readings and pulse oximetry in combination with the defined lack of breathing.

NOTE— Primary central apneas follow the waxing and waning pattern defined as Cheyne-Stokes breathing. Clinical consensus today indicates primary central apneas are best treated using bilevel PAPs with timed backup.

Determining central and non-obstructive apneas is a controversial subject among manufacturers of Autotitrating devices. Some Autotitrating units are limited to flow signals. Due to this limitation, some manufacturers do not attempt to define non-obstructive apneas. Others use questionable definitions such as – any apnea occurring at pressures greater than 10 cmH_2O. (Lab reports substantiate the presence of REM- or position-induced *obstructive* apneas at 10+ cmH_2O. Obstructive apneas *require* a therapy response.) Others, using a clinically unsubstantiated echo concept, pulse pressure into the patient's airway. If the pulse is not returned, the apnea is considered central based on the assumption that 'no echo' indicates an open airway. (This method entirely ignores CSDB or non-obstructive apneas caused by a PAP-induced reduction of carbon dioxide.)

Expiratory Puffs
Expiratory puffing occurs when a patient who normally breathes in and out through the nose begins to exhale in short, high-volume puffs through the lips. Patients usually return to normal nasal breathing patterns after an expiratory puffing event. Reporting puffing is valuable to therapy analysis because, while puffs cause a distorted flow signal, they are also precursors to mouth breathing.

Expiratory puffing is a breathing event often observed in sleep labs during titration.

Therapy Data: Collecting and Reporting

All Autotitrating devices are able to collect patient therapy data and deliver therapy reports. However, differences in manufacturers' breathing event definitions create vast differences between reports. Even minor differences in definition can create false assumptions and may adversely affect therapy. For example:

- Hypopneas defined as a 30% to 50% reduction in amplitude – instead of a 50% reduction – will significantly increase the density of hypopneas reported, possibly causing undue concern regarding therapy efficacy.
- P95 and 95th Percentile reports simply appear to be different names for identical data; however, P95 graphs represent a *specific pressure* at which the Autotitrating device spent 95% of its therapy time, while 95th Percentile graphs the *pressure range* at which the Autotitrating device spent 95% of its therapy time. An incorrect interpretation of the P95 graph could result in either overestimating or underestimating the proper CPAP pressure for the patient.

DEVILBISS AUTOADJUST POSITIVE AIRWAY PRESSURE DEVICE

DeVilbiss has manufactured Autotitrating devices since 1995 giving us significant experience with this technology. DeVilbiss and a now-defunct French manufacturer designed the first flow-based Autotitrating devices for the treatment of OSA, and were the second and third units respectively to receive FDA clearances. These prototypical flow-based Autotitrating devices set the standard for what is today's industry-common technology.

DeVilbiss maintains the AutoAdjust brand name to describe their Autotitrating devices.

Current Technology

Precision Laminar Pneumotach™

One of the core elements of DeVilbiss Autotitrating technology is its Precision Laminar Pneumo-tach's (PLP) ability to create a stable, 'readable' flow signal from the turbulent, patternless flow leaving the PAP's blower. As flow from the Autotitrating unit enters the PLP, it is forced through a series of parallel channels. In the process of squeezing through the PLP's channels, turbulent flow entering the pneumotach is converted to laminar (orderly) flow. Laminar flow "tends to be more orderly and streamlined and to flow in a straight line."[15] This is important because an orderly flow is needed to accurately detect breathing patterns.

As a patient inhales through the PAP interface, flow is drawn out of the PAP's PLP more quickly; whereas a patient's exhalation is forced back through the system causing flow to exit the PLP more slowly. Changes, as small as 1 LPM in patient breathing, are carried back through the PAP creating disturbances in the laminar flow. The PLP uses a mass flow sensor with advanced microstructure technology to translate the laminar flow disturbances into a high-resolution[b], digital signal that mirrors patient breathing patterns. The AutoAdjust algorithm uses this signal to identify breathing events.

All disturbances in the laminar flow pattern are scored by the AutoAdjust's algorithm. Changes caused by the patient's inhalation and exhalation are scored as *normal* breathing events. Changes in the flow signal that meet pre-defined breathing events are scored as *abnormal* breathing events.

Figure 1: Photograph of PLP in IntelliPAP   Figure 2: Illustration of PLP Operation

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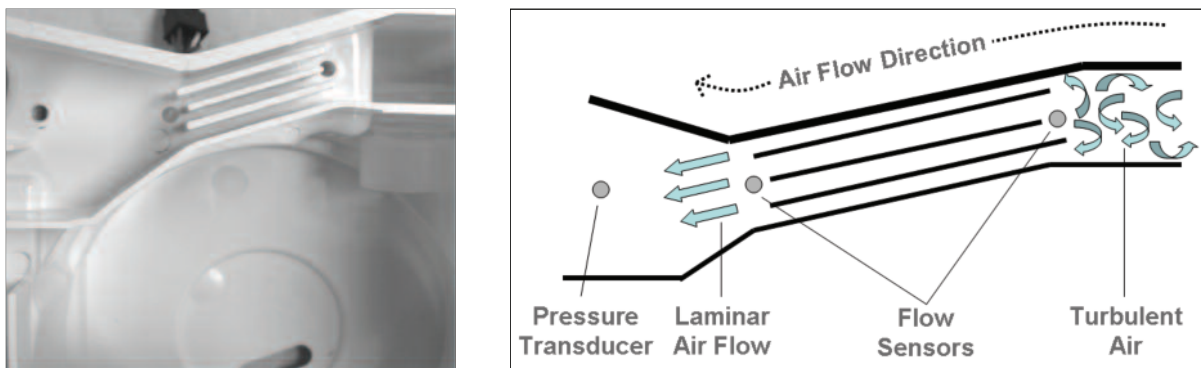[b] The flow sensor is capable of measuring flow changes as low as 0.1 LPM.

Figure 2 illustrates the turbulent, patternless flow and pressure leaving the AutoAdjust's blower through the PLP channels and the orderly patterned (laminar) flow and pressure is shown leaving the channels on its way to the patient. The PLP's flow sensors measure flow using state-of-the-art silicon micromachining. The measurements are processed to create the sensitive and highly responsive flow signal required for accurate event detection.

Pressure Transducer (Sensor)
DeVilbiss uses a pressure transducer, manufactured to precise tolerances, to measure deviations in the orderly pressure created by the PLP. Pressures changes as small as 0.05 cm H_2O are noted by the sensor allowing the algorithm to make pinpoint adjustments in therapy delivery and to record precise measurements on therapy reporting tools.

Event Set Measurement™
DeVilbiss uses its unique Event Set Measurement to increase the algorithm's ability to identify abnormal breathing events and to determine appropriate response speeds. The algorithm uses a series of 6 one-minute windows, collectively referred to as the Event Set, to deliver a comprehensive view of the most recent six minutes of therapy.

The Event Set Measurement updates the algorithm every minute by adding a new *first* window, moving all other windows one-step further along the time continuum, and bumping the previous *sixth* window out of the Event Set Measurement as shown in Figure 3.
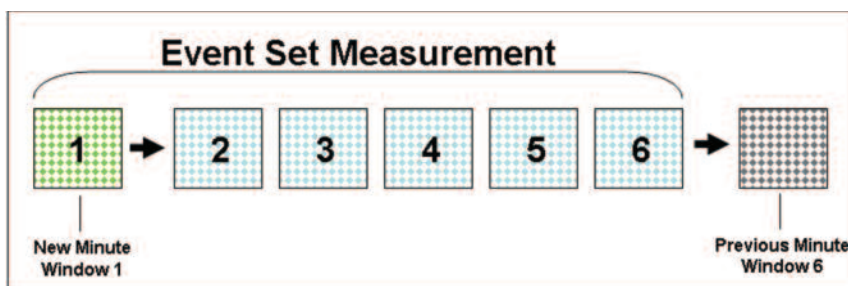

Figure 3: Event Set Measurement minute-by-minute updating process

Using the DeVilbiss Event Set Measurement, the AutoAdjust algorithm is able to mimic the procedures used during a sleep titration when sleep technologists evaluate not only a patient's immediate respiratory events, but also respiratory events in the recent past to make pressure change decisions.[19]

Algorithm

DeVilbiss, in collaboration with a clinical advisory team, developed the AutoAdjust algorithm including the Event Set Measurement. The Event Set Measurement is unique to the DeVilbiss AutoAdjust and allows our devices to make pressure changes every minute and in varying increments which can improve patient comfort and reduce arousals caused by increasing pressure based on a single event, overreacting to artifacts and noise in the signal or decreasing pressures before breathing has stabilized.

The following is a simplified version of algorithmic activity:

- Every 60 seconds, the algorithm adds a new Window-One to the Event Set, shifts all previous windows down the Event Window's time continuum, and bumps the old Window-Six out of the Event Set.
- Every 60 seconds, as they occur during that minute, the algorithm scores all breathing events in Window-One.
- Every 60 seconds, the algorithm searches for density trending using two time periods: the most recent minute (Window-One) and the most recent 6 minutes (the full Event Set).
- Every 60 seconds, the algorithm decides whether to increase, decrease, or maintain the current therapy pressure. If the algorithm determines that a pressure change is beneficial to the patient's therapy, the *incremental* amount of pressure change is also determined at this time.

Some manufacturers and many bench-top studies tout the speed with which some devices respond to events. However, this may not be a viable advantage. Sleep lab titration protocols using manual techniques commonly respond to events as they are seen by the clinician *and* with regard to recent event trending.[19]

There are two reasons for responding less quickly to breathing events: fast response times wake patients or bring them to partial arousal; and fast response times have a greater percentage of false responses. The AutoAdjust mimics sleep lab manual procedures by initiating a moderate and controlled response to breathing events.[19]

The DeVilbiss AutoAdjust algorithm uses snore as precursor to apneas and hypopneas. As mentioned earlier, no clinical studies have found a superior *proactive* event to preventing obstructive events. The AutoAdjust responds aggressively to snoring in an attempt to maintain the lowest Apnea Hypopnea Index (AHI) possible while maintaining the lowest possible pressure to increase patient comfort.

Another feature unique to the DeVilbiss AutoAdjust is the definition and reporting of the expiratory puff. Expiratory puffs can be significant because their presence can interfere with the ability to properly measure patient breathing patterns and can ultimately affect accurate titration. Reporting expiratory puffs alerts clinicians to a possible degradation in the data.

DeVilbiss is not unique in defining or reporting non-obstructive apneas but the AutoAdjust has had this ability as early 1996. In a clinical study comparing DeVilbiss AutoAdjust to sleep lab equipment, Martin Scharf et al found that the AutoAdjust device's definition of non-obstructive apneas had an 85% correlation to the lab's definition of central apneas.[11] The AutoAdjust is NOT attempting to diagnose central apneas; it is, however, able to recognize therapy-induced non-obstructive apneas and, following common lab procedures, stop all pressure increases while these events are present. (Increasing pressure during central apneas can cause further reduction of carbon dioxide levels along with further increases in central and non-obstructive apnea densities.) By defining and reporting non-obstructive apneas, the AutoAdjust offers clinicians a view of non-obstructive apnea density so that they can determine if clinical intervention is appropriate.

Event Definition and Response

The following is an overview of the AutoAdjust algorithm's definition of each abnormal breathing event, its response to the event, and any definition adjustments that are available for customizing the patient's OSA therapy.

Snores

Definition: During inhalation, bursts of low frequency noise vibrations occur within a standard snoring range. Snoring is seen on graphs as a flat, saw-toothed, inhalation wave form.[19]
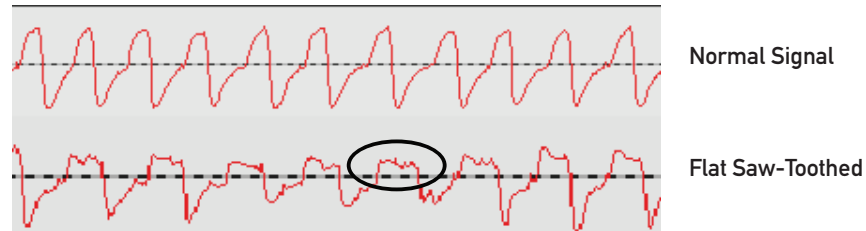
Normal Signal

Flat Saw-Toothed

Figure 4: Snoring signal sample

Response: Snores, as precursors to apneas and hypopneas, are treated aggressively. Pressure increases up to 1 cmH$_2$O per minute until the mix of snores, apneas and hypopneas no longer warrants a higher pressure. After breathing stabilizes, pressure decreases 0.6 cmH$_2$O every 6 minutes until it reaches the lowest pressure setting or until additional breathing events warrant a further response.

Adjustment: Snore response cannot be adjusted.

Obstructive Apneas

Definition: Amplitude is reduced to 10% of full-scale signal for 10 seconds

Full-Scale Signal
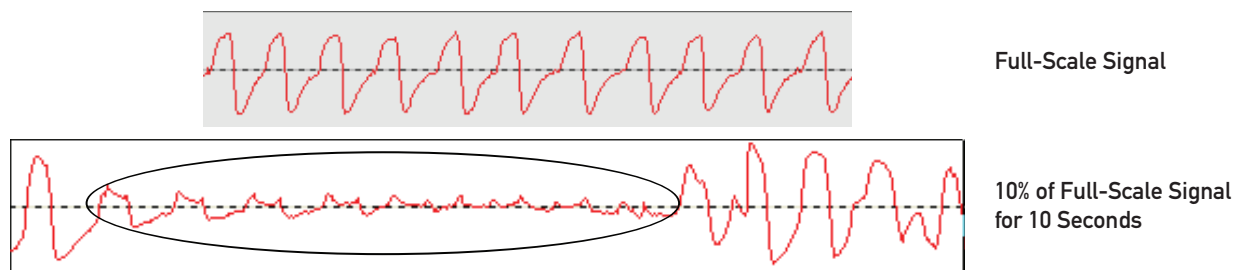
10% of Full-Scale Signal for 10 Seconds

Figure 5: Obstructive apnea signal sample

Response: As described earlier, the AutoAdjust algorithm uses the Event Set Measurement to evaluate the trending in apnea density over a set of six, one-minute windows. If apnea density trends meet specific criteria, the algorithm increases the pressure up to 1 cmH$_2$O per minute until the density trending no longer warrants increased pressure. As apnea density trending decreases, the algorithm decreases pressure 0.6 cmH$_2$O every 6 minutes until it reaches the lowest pressure setting or until breathing events warrant increased pressure.

Adjustment: Default setting is 10% for 10 seconds
Adjustable within the range of 0 – 20% reduction in flow signal for 6 – 150 seconds
• To increase sensitivity, or respond more aggressively to apneas, the apnea percentage should be adjusted toward 20% and/or the duration toward 6 seconds.

- To decrease sensitivity, or respond less aggressively to apneas, the apnea duration can be adjusted to greater than 10 seconds.

An apnea percentage set to 0% will disable the ability to score apneas. All reductions in flow will score as hypopneas. An apnea percentage set to 5% will disable the ability to score non-obstructive apneas as separate from obstructive apneas. All apneas below the 5% threshold will score as obstructive apneas.

Hypopneas
Definition: Amplitude is reduced to 50% of the most recent baseline signal for 10 seconds.
NOTE: The AutoAdjust algorithm constantly adjusts the full-scale signal to match the patient's current breathing pattern: therefore, the amount of signal loss needed to reach a 50% reduction in amplitude will vary.
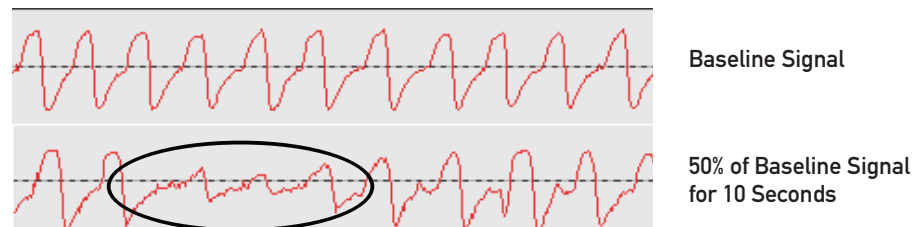

Baseline Signal

50% of Baseline Signal for 10 Seconds

Figure 6: Hypopnea signal sample

Response: The algorithm also uses Event Set Measurement to evaluate the trending in hypopnea density seen in Window-One and the Event Window. If hypopnea density trends meet the specific criteria, the algorithm increases the pressure up to 1 cmH$_2$O per minute until the density trending no longer warrants increased pressure. As hypopnea density trending decreases and criteria for the increased pressure ceases to be met, the algorithm decreases pressure 0.6 cmH$_2$O every 6 minutes until it reaches the lowest pressure setting or until breathing events warrant increased pressure.

Adjustment: Default setting is 50% for 10 seconds.
Adjustable within the range: 30 – 70% reduction in flow signal for 6 – 150 seconds
- To increase sensitivity, or respond more aggressively to hypopneas, the hypopnea percentage can be adjusted toward 30% and/or the duration toward 6 seconds.
- To decrease sensitivity, or respond less aggressively to hypopneas, the hypopnea percentage can be adjusted toward 70% and/or the duration to greater than 10 seconds.

Leaks
Cause: Mask fit leaks, tubing leaks, and mouth breathing.
NOTE: Some normal mask venting flow rates, or bias flow, may be higher than 60 LPM. Some manufacturers only compensate for the bias flow associated with their mask brands. DeVilbiss delivers accurate pressures with 95 LPM bias flows, which includes compensating for venting leaks that accompany most full face masks, and continues to perform at bias flow volumes higher than 95 LPM.

Definition: Flow is greater than 95 LPM.
NOTE: Leaks above 95 LPM are visible as a loss in the ability to measure signal amplitude.

Normal

Loss of Amplitude Measurement
Increase in Blower Speed
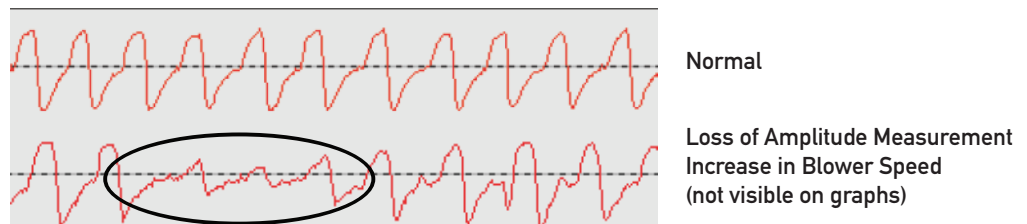(not visible on graphs)

Figure 7: Leak signal sample

Response: The AutoAdjust algorithm increases pressure to maintain the flow necessary for therapy. Since leak rates greater than 95 LPM cause irregular (noisy, random) flow signals, the AutoAdjust algorithm can no longer properly detect breathing events, so event response is disabled; however, following procedures similar to those used in sleep labs, the algorithm decreases pressure every 6 minutes until the patient changes body or mask position to resolve the leak or stops mouth breathing. Increasing pressure during leak events can cause an increase of the leak, instead of a reduction. When the leak rate is reduced sufficiently to allow proper event detection, the algorithm enables normal event response.

NOTE: It is important to track leaks because leak times ≥ 10% of the total therapy time may require clinical intervention, such as refitting the mask or moving to a chin strap or full face/dual airway mask.

Adjustment: Leak response cannot be adjusted.

Expiratory Puffs

Cause: Breathing in through the nose and out through loosely closed lips in short puffs.

Definition: Flattening of expiration wave form.
NOTE: Expiratory puffing is visible as a tail on the end of an expiratory wave form, instead of the usual curve.
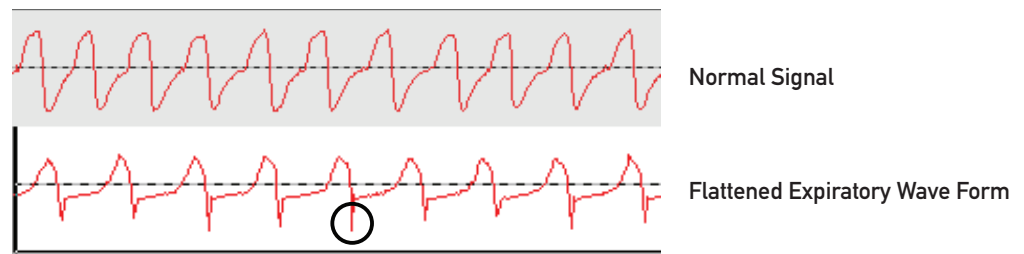

Normal Signal

Flattened Expiratory Wave Form

Figure 8: Expiratory puff sample

Response: No change to pressure. DeVilbiss is unique in reporting expiratory puffing. This breathing pattern can create a poor signal and interfere with titration and therapy. The AutoAdjust tracks expiratory puffs, but does not respond. Increasing pressure would not reduce puffs and may increase puffs. Exhale puffing in excess of 30 per hour should be monitored. If the number recedes with therapy, allow it to continue its downward trend; otherwise clinical intervention may be required, such as a chin strap or full face/dual airway mask.

Adjustment: Expiratory puff response cannot be adjusted.

Non-Obstructive Apneas (NOAs)

Cause: Non-obstructive apneas may occur during OSA therapy if the PAP pressure reduces the normal carbon dioxide accumulation and degrades the CO_2 stimulus response. NOAs also may be primary central apneas that cannot be properly defined by an Autotitrating device alone.

        NOTE: Non-obstructive apneas in excess of 10 per hour could indicate primary central apneas, not NOAs or obstructive apneas, and clinical intervention may be required.

Definition: Amplitude is reduced to 5% or less of normal signal for approximately 10 seconds.
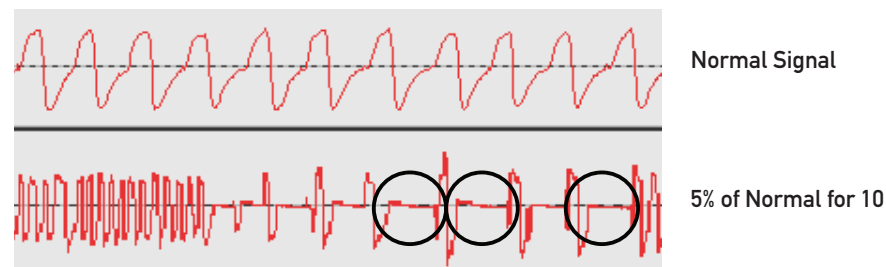
Normal Signal

5% of Normal for 10

Figure 9: Non-obstructive apnea

Response: No change in pressure. The AutoAdjust PAP tracks non-obstructive apneas, but does not respond.

Adjustment: Non-obstructive apnea response cannot be adjusted. A non-obstructive apnea's *non-response* however can be overridden by changing the obstructive apnea percentage setting to 5 or less. This setting change will force the AutoAdjust to define non-obstructive apneas as obstructive apneas and respond accordingly.

THERAPY DATA MANAGEMENT

The DeVilbiss IntelliPAP AutoAdjust features two options for collecting, analyzing, and reporting therapy data including Adherence Score information required by Medicare: the SmartLink® Therapy Management System and the SmartCode® Remote Data Retrieval System.

- The SmartLink system provides daily-detailed information as well as summary information. This management system transfers data between a patient's device and the software on the provider's or clinician's computer via data card.
- The SmartCode is built-in to each IntelliPAP system and provides summary data for 1-, 7-, 30-, and 90-day timeframes. With the SmartCode system, summary data is easily collected with a simple telephone call to the patient.

SmartLink® Therapy Management System

The SmartLink therapy management system is an optional reporting tool that consists of desktop software, a snap-on communication module, a memory card, and a card reader. In addition to its uses as an inventory tool for homecare providers and a therapy reporting tool for physicians and clinicians, SmartLink therapy management allows *remote* changes to pressure settings and event definitions.

SmartLink reports are based on *cumulative* usage records for high level Summary views but also provide 1-Night views for in-depth details on daily use. Both Summary and 1-Night reports are customizable and include Medicare's Adherence Score.

DeVilbiss Adherence Scoring

Unique to all DeVilbiss IntelliPAP brand models, therapy reports provide an Adherence Score based on the Medicare-established criteria for PAP adherence, defined as, "...use of PAP greater than or equal to 4 hours per night, on 70% of nights, during a consecutive 30-day period during the first 3 months of initial usage."[9]

NOTE: Adherence Scores can be manually set for 5 hours of required nightly usage, if desired.

Summary Reports

Summary reports are high level views of usage and time-at-pressure for adjustable date ranges, and provide numerical reports on adherence information:

- Total number of days in the selected range
- Number of days with any usage
- Number of days with at least 4 hours of usage
- Usage index – percentage of days with at least 4 hours of usage
- Average usage duration
- Standard deviation – with lower numbers indicating greater conformity

Summary reports also provide graphical reports:

Hour-by-Hour Usage
Hour-by-Hour Usage shows the time the patient started and ended therapy each day within a
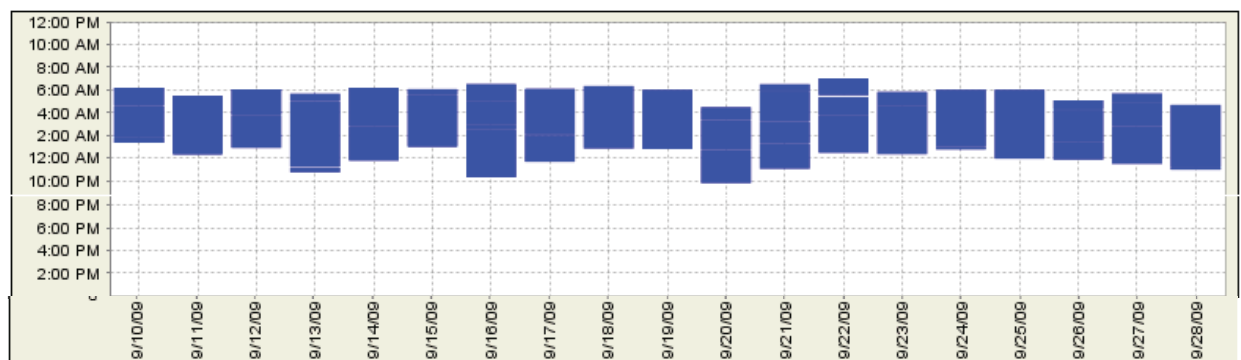
chosen time period. It also shows breaks in the usage.
Figure 10: Hour-by-Hour Usage

Hours of Usage
Hours of Usage shows the amount of time the patient spent on therapy each day within the chosen time period. It also clearly marks the minimum usage of 4 hours; so days below this threshold are easily flagged.
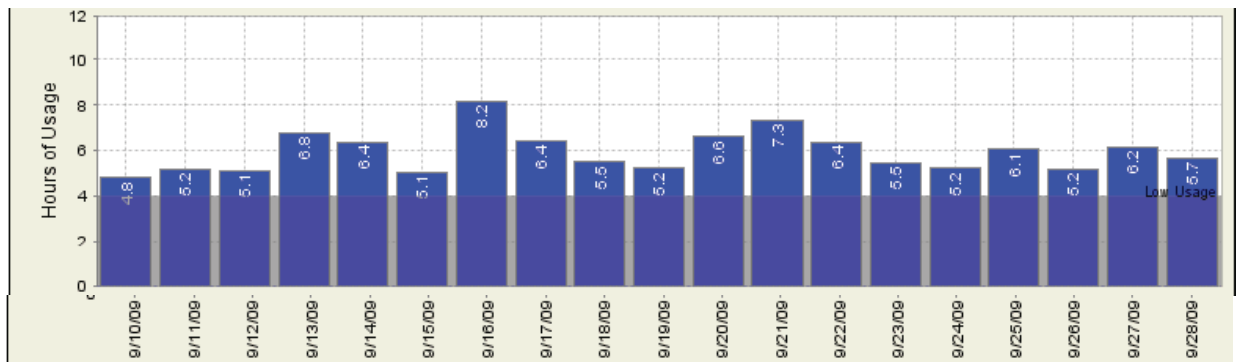
Figure 11: Hours of usage

Pressure Trending

Trending is provided for both maximum pressure and average pressure to help physicians/clinicians determine both a fixed pressure for CPAP settings and proper upper and lower pressures for AutoAdjust settings. The current upper and lower pressure settings are drawn on the graph. The average pressure is shown as a blue column with the maximum pressure added to the column in red.
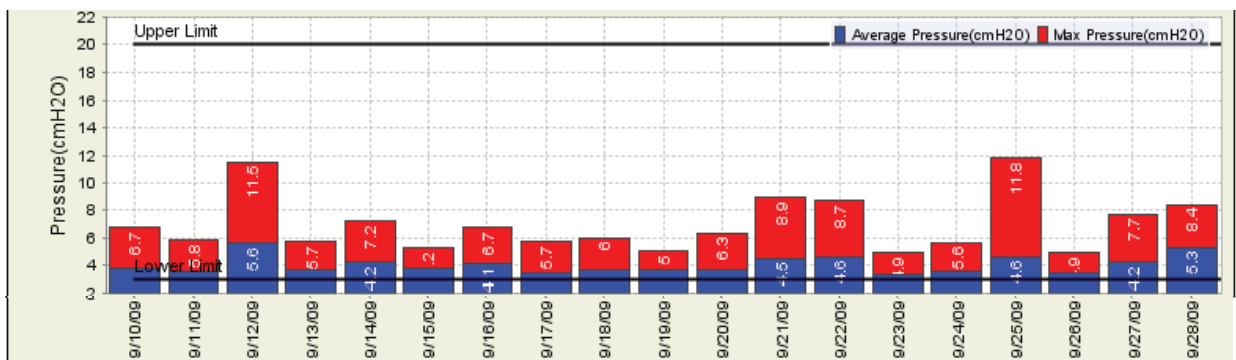

Figure 12: Pressure trending

Leak Rates

All recorded leak rates are shown so that clinicians can observe the trending of any excessive leak rates. Most masks expiratory port leak rates are between 30-40 LPM. The IntelliPAP AutoAdjust considers leak rates greater than 95 LPM to be excessive.
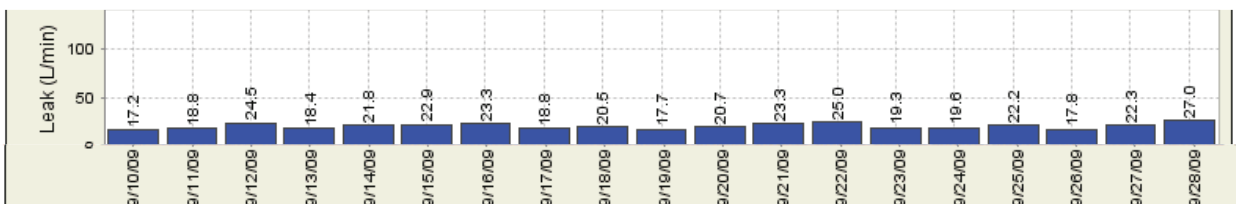

Figure 13: Leak rates

Apnea/Hypopnea Index (AHI)

AHI is the number of apneas and hypopneas per hour. This number should be less than 10 per hour while on an autotitrating PAP, according to Dr Berry's group.[3]
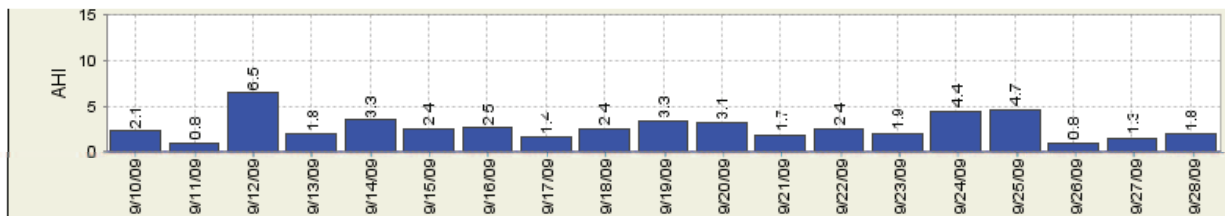

Figure 14: AHI

1-Night Reports

1-Night reports are highly detailed views of usage, events and time-at-pressure for any *one* day in therapy history. Sessions are selected from a drop-down list.

1-Night reports provide numerical data for the selected session starting with the time spent at Delay pressure and continuing through the time spent in therapy:

Events Summary (Delay Mode)				Events Summary (AutoAdjust Mode)			
Time:	1 Hours	Mask Leak Time:	0 % of total	Time:	6.7 Hours	Mask Leak Time:	0 % of total
AHI:	4 Per Hour	EPI:	1 Per Hour	AHI:	2.1 Per Hour	EPI:	7.9 Per Hour
AI:	2 Per Hour	Average Pressure:	8 cmH2O	AI:	0.9 Per Hour	Average Pressure:	13.5 cmH2O
HI:	2 Per Hour	Average Leak:	38.1 L/min	HI:	1.2 Per Hour	Average Leak:	45.8 L/min
NRI:	0 Per Hour	Avg. Est. Tidal Vol.:	608.3 mL	NRI:	0.1 Per Hour	Avg. Est. Tidal Vol.:	729 mL
Snores:	37 Events	Avg. Breath Rate:	15 bpm	Snores:	154 Events	Avg. Breath Rate:	13.5 bpm
				Max Pressure:	16.0 cmH2O		

Figure 15: 1-Night report

1-Night report graphs are displayed so that events and pressure changes are easily correlated.

Hourly Pressure

Hourly pressure reports include the time and pressure spent in Delay mode, breaks in the therapy session, upper and lower pressure settings, 90th percentile pressure, and variations in the pressure during the chosen night's therapy session.
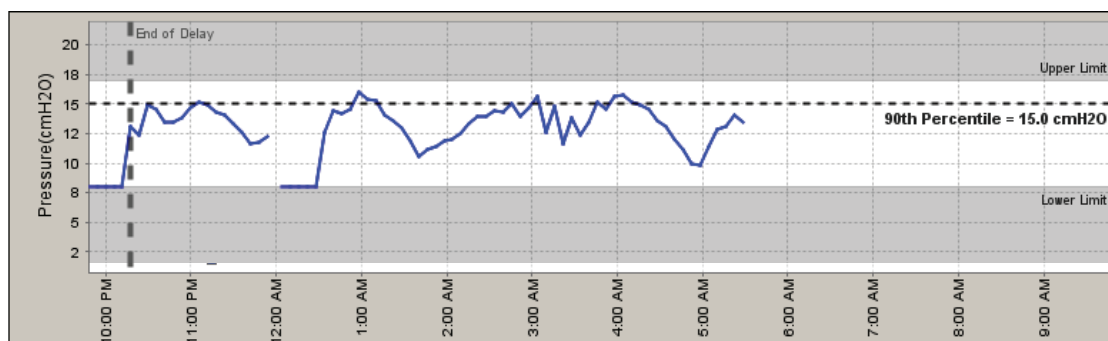

Figure 16: Hourly pressure

Hourly Leak Flow Rate

Hourly leak reports show maximum and average leak rates for each hour of therapy. The graph calls out the 10 highest flows during the past hour and the corresponding average flows for the same time period. The maximum leak usually rides in parallel above the average leak line.
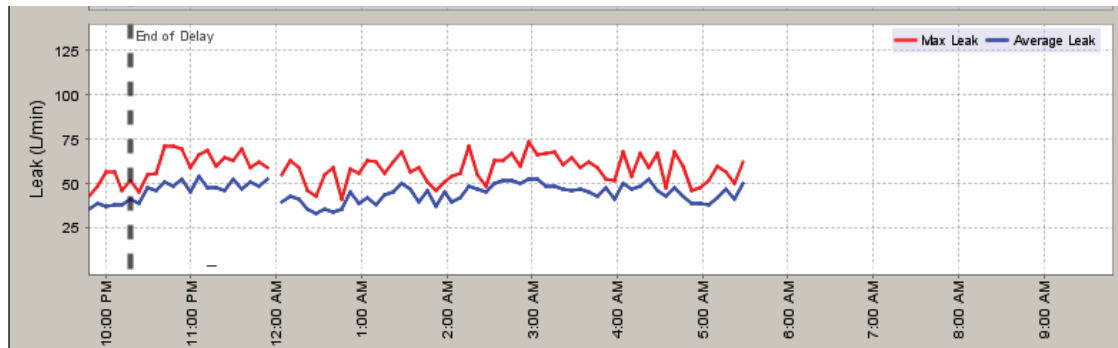

Figure 17: Hourly leak flow rate

Hourly Event Density

All abnormal breathing events tracked by the PAP are displayed on the Hourly Event Density graph. The events are tracked in 6 minute windows (10 periods in each hour). The following table lists initials with their corresponding breathing event and the number of events depicted by each color block on the graph below.

Initial	Event	Density during 6 minute period
A	Apnea	Each event
S	Snore	Three or more events
H	Hypopnea	Each event
E	Exhale puff	Six or more events
L	Leak	Each event > 95 L/min
M	Mixed/Non-responding (NR)	Each event

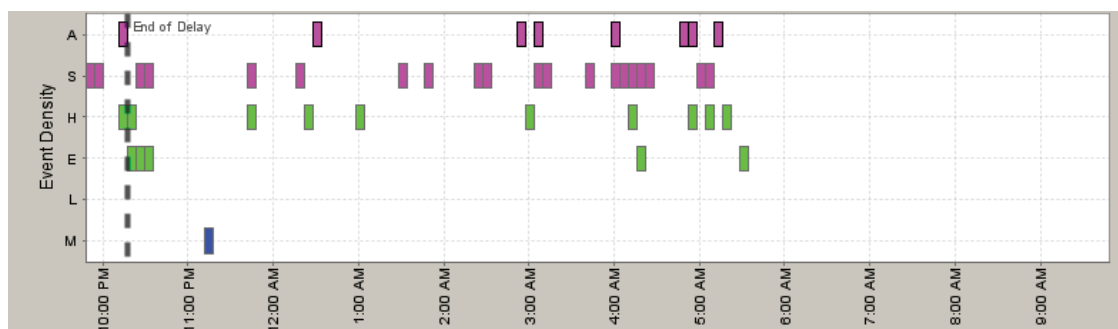Figure 18: Hourly event density table

Figure 19: Hourly event density graph

SmartCode® Remote Data Retrieval System

SmartCode data retrieval is a standard feature on all IntelliPAP brand models. SmartCode reports are based on *summary* usage records. In addition to providing a Medicare-specific Adherence Score, the IntelliPAP AutoAdjust generates codes that, when entered into the report generator, are deciphered to provide cumulative usage reports. SmartCode reports provide information in numerical and graphical formats in several time frames:

- The last day the device was used
- The last 7 days of use
- The last 30 days of use
- The last 90 days of use

The Adherence Score is based on the following:

- Daily Usage: The total hours of continuous usage during a 24-hour period
- Therapy Period: The first 90 24-hour periods following the patient's first PAP use
- Scoring Period: Any 30 consecutive 24-hour periods within the therapy period
- Adherence Score: The percentage of days, within any scoring period, where daily usage is greater than or equal to 4 hours of continuous, allowing for short breaks during use.

To comply with Medicare requirements, the Adherence Score must be at least 70%, which is least 21 out of 30 consecutive days in the scoring period. In order to report the best score available for each patient, SmartCode scans the entire therapy period and returns the best 30 consecutive days.

Daily Data

Daily data is provided as a numerical count of days during which the patient has been breathing on the AutoAdjust device for at least 4 continuous hours, including: the number of days in the time period, the number of days used at least 4 hours, and the percentage of days used at least 4 hours

Usage Data

	Last 90 Days	Last 30 Days	Last 7 Days	Last Day
% Days at least 4 hours	64%	67%	100%	100%
Day Count	90	30	7	1
Days at least 4 hours	58	20	7	1
95th Percentile Pressure	9.5	9.5	9.0	9.0
90th Percentile Pressure	8.5	8.5	8.0	8.0
AHI	5.5	5.5	5.0	5.0
Pressure Plateau Time	3%	1%	1%	2%
High Leak Flow Time	2%	2%	3%	1%
NRI	1.75	1.50	1.00	0.25
EPI	2	2	3	1
SmartCode	7MTJT-47D9-7DT7L	DXY4-3D97-DJ7Y	3CCC-379D-7D75	F6CD-39F-3570
While Breathing Hours Last Day				5.1
Adherence Score	67% (20/30)			

Cumulative Usage

% Days at least 4 hours	Day Count	Days at least 4 hours	Average Hours Per Day	While Breathing Hours	SmartCode Usage
66%	101	67	6.2	627	ZD7-79FK-K7X

Figure 20: Daily data

95% Percentile Pressure
90% Percentile Pressure

Percentile pressure is provided as a number and as a graph. Percentile pressure indicates that therapy pressure was *at* or *below* this pressure for 90- or 95-percent of its usage time. Percentile pressure can be used to help choose fixed CPAP pressures. If the AutoAdjust device operates at the upper pressure setting for more than 10% of the therapy time, this may be an indication that the upper setting should be increased. *Refer to Pressure Plateau Time

Apnea/Hypopnea Index (AHI)

AHI is provided as a number and as a graph. AHI is the average number of apneas and hypopneas per hour. This number should be less than 10 while on an Autotitrating PAP, according to Dr. Berry's group.[3]
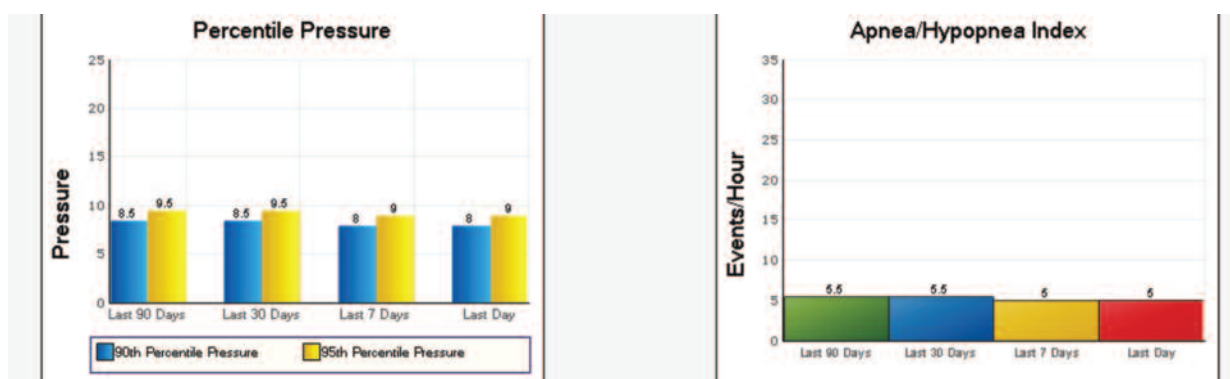

Figure 21: AHI

Pressure Plateau Time

Pressure plateau time is provided as a number and as a graph. Pressure plateau time is the percentage of time therapy was at the upper prescription limit. If the time is 10% or higher, the pressure has been *railing* at the upper pressure and this may be an indication the prescription setting should be increased to allow the therapy to move to a higher pressure than is currently allowed.

High Leak Flow Time

High leak flow time is provided as a number and as a graph. High leak flow time is the percentage of time the leak was above 95 LPM. (Normal mask vent leaks are expected to be in the 30-40 LPM range.) If high leak flow time is 10% or greater, it indicates a possible issue with either mouth breathing, mask fit, or that clinical intervention is necessary.
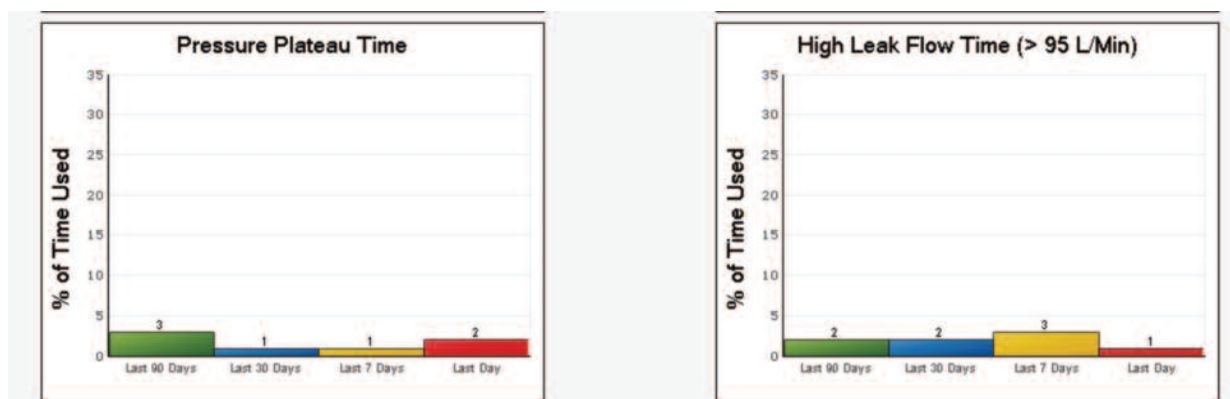
Figure 22: Pressure Plateau Time (left) and High Leak Flow Time (right)

Non-Responding Event Index (NRI)

NRI is provided as a number and as a graph. The NRI includes all the non-responding events considered by the AutoAdjust PAP: leaks, non-obstructive apneas, and exhale puffs. The NRI is the average number of non-responding events per hour. If the number is higher than 10, the patient may be exhibiting primary central apneas and need clinical intervention.

NOTE: If non-responding events are present, the algorithm prevents a further increase in pressure because increasing the pressure in the presence of these events is thought to produce central apneas which could be detrimental to a patient with obstructive sleep apnea.3

Exhale Puff Index (EPI)

EPI, unique to DeVilbiss AutoAdjust devices, is provided as a number and as a graph. Exhale puffs are a breathing pattern described as 'in through the nose and out through the lips'. EPI is the number of exhale puff events detected per hour. If exhale puffs are present in significant numbers, the AutoAdjust algorithm will prevent the pressure from increasing because an increase in the
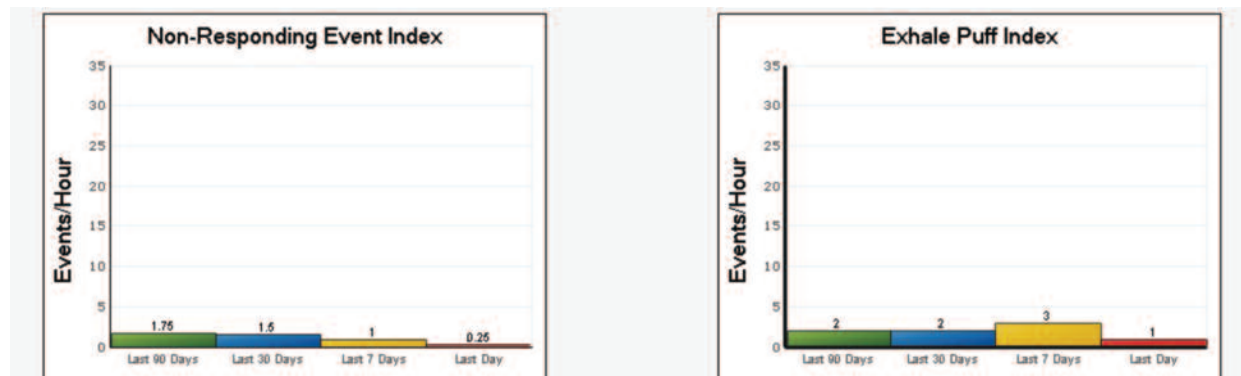
pressure will create more exhale puffs in a patient with obstructive sleep apnea.

Figure 23: NRI (left) and EPI (right)

COMPETITIVE TESTING AND COMPARISONS

Some comparisons reveal true similarities and differences between products, but some are misleading. As discussed below, test results vary due to test equipment and its associated limitations and/or the study's design and protocols.

Bench-Top Studies

These studies are conducted on a simulated lung model; however, there are limitations to applying bench-top study methods to Autotitrating devices. As recently as September 2009, McCoy et al published a paper suggesting that there is a lack of "details on the algorithm used in each APAP device"[16] and further questioning the lack of "current, objective research indentifying the capabilities and limitations of each device."[16] When reading bench-top study findings and conclusions, the following issues *must* be considered:

Response triggers

As mentioned earlier, Autotitrating devices differ according to which events their algorithms use as response triggers. Erroneous conclusions may result if the bench-top study expects the device to respond to events that are not response triggers in the algorithm being tested.

For example, some devices use flow limitation as a response trigger, while other devices use snoring. Flow limitation is easily tested on a simulated lung model; while testing a snore trigger can be very difficult. Autotitrating devices that use snoring score poorly on bench-top studies that test a response to flow limitation, including the testing done by McCoy et al: "...the lack of a snoring component may have contributed to the minimal response on the part of..."[16] (several units during the flow-limitation testing).
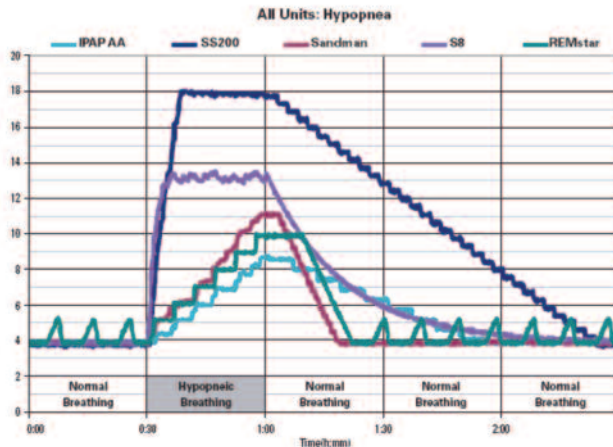

Figure 24: First test by McCoy et al

Recently, Valley Inspired Products conducted a bench-top study using a 'snore box' and found " the snore signal did have a significant impact on the response"[17] and "yielded a more rapid pressure response,"[17] correcting previous bench-top study findings.
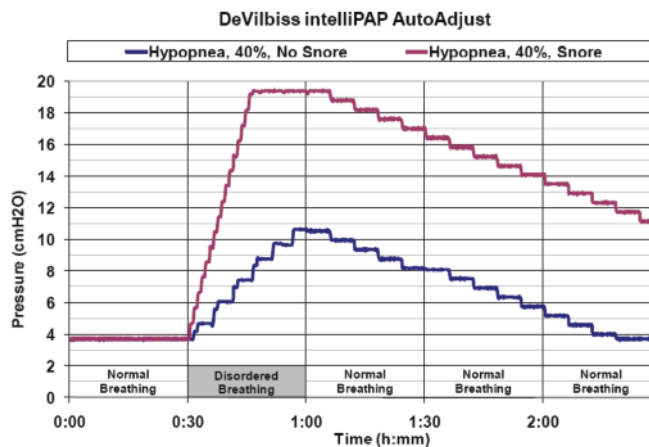

Figure 25: Second test by Valley Inspired Products (w/snore box)

Event definitions

Autotitrating units also differ according to the criteria used to define specific respiratory events. Testing bodies may set definitions without regard for the criteria used by each Autotitrating device being tested. A 2006 McCoy article found, "Our research has determined that all APAPs are different, based on the algorithm that controls the device's response to a breathing signal."[18] Even a small deviation in definition, such as using a *range* of criteria instead of using a *specific* criterion, will produce erroneous conclusions.

For example, the test lung model may be programmed to create hypopneas using the criteria: any flow signal reduction between 30% and 50%. Autotitrating devices that define hypopneas with a specific reduction of 50% will miss a majority of the lung-created hypopneas and those units – waiting for a reduction of 50% before responding – will appear to fail the hypopnea response test, when in fact they are responding exactly as intended. Adjustable Autotitrating devices usually offer a variety of reduction values for hypopnea definition; however they usually only use one value at a time.

Clinical Studies

There are limited clinical studies comparing the response of Autotitrating devices. As of 2001, there were no articles comparing Autotitrating devices.[3] Several factors may contribute to this dearth of information. Prime among them are the costs associated with clinical studies, the taint of bias assumed when the study is 'purchased' by a manufacturer, and the lack of industry-accepted standards with which to compare Autotitrating units.

In 2002, Dr. Berry, et al, "assigned the task of developing a critical review of the literature pertaining to the treatment aspects of APAP devices,"[3] found that analysis was complicated for a variety of reasons:

- Autotitrators vary to such a degree that findings from one device may not apply to another Autotitrator.
- Many studies were designed to show the feasibility and efficacy of a particular Autotitrating unit, but not in comparison to other sleep therapy devices, such as other devices or placebos.
- Some studies may have had an unintentional selection bias.
- Study designs varied significantly, even during controlled trials.

Most clinical studies involving Autotitrating devices were, and are, designed to compare these devices to fixed CPAP devices, the 'gold standard' in OSA therapy. Among an extensive list of needed clinical studies, Berry's group cited the need for more "data comparing the effectiveness of different APAP technologies."[3] Seven years later, McCoy et al found that little had changed: "There are no standards established for the appropriate pressure response to a specific breathing pattern as there do not seem to be research sites or standards agencies that are looking at this issue."[16]

One study, done by Senn and colleagues, compared the DeVilbiss AutoAdjust device to the ResMed® AutoSet™ device. The study found that both units had *similar clinical results* and concluded that *no significant variations* in objectively measured vigilance, nocturnal breathing disturbances or symptoms indicated that either of the treatment modalities was superior. The study further stated that "Most studies have shown parity of devices rather than major differences"[10].

CLINICAL VALUE

As mentioned previously in this paper, some early Autotitrating devices had limitations which gave a long-lasting negative impression of how all such devices functioned. Recent testing has shown that Autotitrating devices now are equal to or, in some cases, better than fixed CPAP devices in a variety of parameters. The DeVilbiss IntelliPAP AutoAdjust device has clinically acceptable criteria for defining respiratory events and responding to those events. The following literature references support Autotitrating technology in treating patients with obstructive sleep apnea.

Leak Rates and Respiratory Effort Related Arousal (RERA)

Using previously published documents, in 2002 Berry, et al warned: Autotitrating devices have limited capabilities at high leak rates and with the presence of RERAs.[3]

DeVilbiss Autotitrating devices have always attempted to maintain proper event response during high flow leaks. Early DeVilbiss devices disengaged the algorithm's event response if leak rates increased flow above 70 LPM. With improved technology in signal creation and detection, the AutoAdjust has been maintaining effective event detection and response while handling leak rates up to 95 LPM. The AutoAdjust is able to maintain therapy pressures at even *higher* leak rates; however, it freezes further event detection at these higher rates in an effort to eliminate potentially faulty pressure responses caused by the coincident increase in signal noise instead of actual breathing events.

With regard to DeVilbiss AutoAdjust's ability to respond to RERAs, please consider the following: an Autotitrating device's definition for hypopneas is somewhat similar to the definition for RERAs; the AutoAdjust has adjustable definitions for hypopneas. Lowering the hypopnea definition's percentage of signal reduction to 30% may allow the AutoAdjust to respond to possible RERAs, *if the physician or clinician noticed RERAs during the lab titration.*

NOTE: DeVilbiss has NO clinical studies to demonstrate the effectiveness of this approach to RERAs. The hypothesis has been presented to a number of clinicians with an overwhelming majority agreeing that the theory was sound.

Reduction of AHI

As early as 1997, Stradling et al found Autotitrating devices equal to fixed CPAPs in reducing AHI indexes: "A total of nine clinical series, one non-randomized control trial, and 16 randomized controlled trials found that APAP reduced the apnea plus hypopnea index to acceptable levels (AHI <10/hr) in greater than 80%-95% of the OSA patients studied."[2] At least three of these studies were conducted with a DeVilbiss AutoAdjust device.[3,4,6,8,13,14]

Sleep Quality and Subjective and Objective Measures of Daytime Sleepiness

In the study cited above, Stradling et al using 26 study/trial reports, found Autotitrators better than fixed CPAPs in providing quality sleep: "In general, the literature documents that APAP significantly improves sleep quality."[2] At least two of these studies were by researchers using a DeVilbiss AutoAdjust device.[3,8,11,13,14]

Nocturnal Desaturation

There is well documented consensus that Autotitrating PAP devices, including the DeVilbiss IntelliPAP AutoAdjust, reduce oxygen desaturation within accepted limits.[3,4, 8, 9] Stradling et al found autotitrators equal to fixed PAPs concerning desaturation: "In summary, evidence to date suggests that APAP prevents significant desaturation in most OSA patients."[2] At least one of these studies was by researchers using a DeVilbiss AutoAdjust device.

Using APAP Titration for Fixed PAP Therapy

In the previously cited 2002 paper, Berry et al found a good correlation between using APAP titration techniques and manual titration techniques in choosing fixed PAP pressures.[3]

A study by Stradling et al, with a DeVilbiss AutoAdjust device, demonstrated a strong correlation between APAP and manual titration techniques. Dr Stradling also found improved therapy acceptance following APAP titration – with 73% of APAP titrated patients accepting therapy vs. 64% of manually titrated patients. He also found that patients who refused to accept therapy showed a higher incidence in the manual titration group where 13% of manual titrated patients declined therapy vs. 2% of APAP titrated patients.[2]

In 2000, Rick Fletcher et al found that 30 out of 35 patients titrated and treated with a DeVilbiss AutoAdjust device continued therapy after titration.[7]

Patient Satisfaction

In 2000 and 2006, Fletcher and Senn respectively conducted studies using a DeVilbiss AutoAdjust device and found APAP had some improvement in adherence over CPAP.[6,7] Two additional studies found patient preference was for APAP over fixed CPAP.[4,12,13,14]

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